K082157

510(K) Summary

AUG - 6 2008

A. Submitter Information

Submitter's Name:	Kettenbach GmbH & Co. KG
Address:	Im Heerfeld 7 D-35713 Eschenburg, Germany
Phone Number:	(+49) 2774-705-58
Fax Number:	(+49) 2774-705-33
Contact Person:	Michaela Zinke
Date of Preparation:	June 19th , 2008

B. Device Name

Trade Name:	*Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials*
Common/Usual Name:	Impression Material
Classification Name:	Material, Impression (21 CFR 827.3660, Product Code: ELW)

C. Predicate Devices

Trade Name:	Freealgin, (K070700)
Trade Name:	Position Penta, Position Penta quick (K974231)
Trade Name:	Alginot (Kerr VPS Impression Material) (K 050604)

D. Device Description

Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials are addition-curing, elastomeric preliminary impression materials, to be used as an alternative to traditional alginate materials. They differ in their curing times, final hardnesses, and recovery from deformation.

E. Intended Use

Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials are addition-curing, elastomeric preliminary impression materials, to be used as an alternative to traditional alginate materials.

Indications for Use

Kettosil, Silginat and Silginat Strawberry are suitable for impressions in preparation of:

- Preliminary impression
- Anatomical models
- Fabricating temporary crowns and bridges
- Opposing dentition
- Fabricating simple removable prosthetic restorations
- Orthodontic work
- Fabricating removable retainers and splints
- Case study models
- Producing models for the construction of trays for whitening solutions, bites and surgical guides.

F. Technological Characteristics Summary

The technological characteristics of *Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials* are substantially equivalent to the predicate device technological characteristics. *Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials* and the predicate devices are addition-curing, elastomeric preliminary impression materials, designed and manufactured to be used as an alternative to traditional alginate materials.

G. Performance Data

Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (FOD#2203, 8/17/1998), ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor 1:2004/Amd 1:2007.* The results of device performance testing demonstrated that *Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials* are suitable for use as preliminary impression materials, to be used as an alternative to traditional alginate materials.. *Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials* have been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

Kettenbach GmbH & Co. KG
C/O Mr. Steffan Preiss
Responsible Third Party Official
TUV SUD America, Incorporated
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K082157
Trade/Device Name: Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 29, 2008
Received: July 31, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I-D

Indications for Use

510(k) Number (if known): K082157

Device Name: *Kettosil® and Silginat® (Silginat®, Silginat® Strawberry) Impression Materials*

Indications for Use:

Kettosil, Silginat and Silginat Strawberry are suitable for impressions in preparation of:

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- Fabricating removable retainers and splints
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- Producing models for the construction of trays for whitening solutions, bites and surgical guides.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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